

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA**

MARGUERITE SMITH, on behalf of
herself and all others similarly situated,

Plaintiff,

v.

SOCLEAN, INC.,

Defendant.

Case No.

**CLASS ACTION
COMPLAINT**

DEMAND FOR JURY TRIAL

Plaintiff Marguerite Smith (“Smith” or “Plaintiff”) on behalf of herself and a class of all others similarly situated as defined below, for their complaint against Defendant SoClean, Inc. (“SoClean”), allege as follows:

INTRODUCTION

1. Since approximately 2012, SoClean manufactured and marketed devices used to clean continuous positive airway pressure (“CPAP”) machines. SoClean concealed and omitted material information on the presence and risk of ozone exposure from the SoClean 2 CPAP Sanitizing Machine, the SoClean 2 Go CPAP Sanitizing machine, and their predecessor devices (collectively “the SoClean devices”). The SoClean devices work by generating ozone to sterilize and deodorize CPAP machines. Ozone (O₃) is an unstable toxic gas with a pungent characteristic odor that can kill bacteria and viruses. To be effective as a germicide, ozone must be present in a concentration far greater than can be safely tolerated by humans or animals.

2. SoClean’s marketing materials fail to disclose that its devices emit ozone, which is a longstanding requirement of federal law. Instead, SoClean falsely represents that its devices use “activated oxygen” to clean CPAP machines. SoClean markets the devices as “safe” and

“healthy,” which is false given that they generate toxic ozone gas at levels that substantially exceed federal regulations. SoClean falsely represents that its devices use “no water or chemicals” or “no harsh chemicals” to clean CPAP machines, despite using ozone gas – a harsh chemical that causes respiratory problems in humans. SoClean represents that its devices use the same sanitizing process found in “hospital sanitizing,” however, hospitals cannot and do not use ozone sanitizers in spaces occupied by patients. SoClean also claims that separately sold filters convert “activated oxygen” into “regular oxygen,” which is false because SoClean’s filters have no measurable effect on the device’s ozone output. Finally, SoClean falsely claims that its devices are “sealed” such that “activated oxygen” (*i.e.*, ozone) does not escape the devices.

3. SoClean’s violation of federal regulations as well as its misrepresentations, concealment, half-truths, and omissions have allowed it to command ninety-percent of the relevant market. Due to the nature of SoClean’s business, its customers all are ill or infirm because they have breathing problems for which they are receiving medical treatment in the form of CPAP therapy. If CPAP users knew that the SoClean devices generate unsafe levels of toxic gas, which is then pumped into their CPAP machines and into their bedrooms, they would find this risk material to their purchasing decisions.

4. SoClean’s representations are designed to mislead consumers into believing that the machine uses a benign form of oxygen to clean CPAP machines rather than a harsh gas that is generally only suitable for commercial sanitization under highly controlled conditions. These misrepresentations, concealment, half-truths, and omissions are made more egregious because the SoClean devices are designed and marketed for use on the consumer’s bedside table and because CPAP users suffer from many symptoms that ozone exposure exacerbates – making the falsehoods especially reprehensible and dangerous.

PARTIES

5. Plaintiff Marguerite Smith resides in the city of Holly, in Gaston County, North Carolina. In or around October of 2018, Plaintiff purchased a SoClean 2 device to clean her ResMed CPAP machine. Plaintiff Smith considered the ability to sanitize her device, her safety, and the price when she made her purchasing decision. She would not have purchased the SoClean 2 if she knew what she knows now about the SoClean 2. She also paid more for the SoClean 2 devices because she believed the product used activated oxygen and was safe and healthy.

6. Prior to purchasing her SoClean device, Plaintiff Smith saw Defendant's claims on the packaging claiming the device used activated oxygen and was safe and healthy, and she relied on these representations in purchasing the device. During that time, based on Defendant's omissions and the false and misleading claims, warranties, representations, advertisements, and other marketing, Plaintiff Smith was unaware that these products emitted ozone, and would not have purchased the device or paid as much for it if that information was fully disclosed. Plaintiff Smith was injured by paying a premium for a device that has no or very little value—or whose value was at least less than what she paid—based on the presence of ozone. Plaintiff Smith has suffered eye irritation, respiratory tract irritation, headaches, shortness of breath, and increased frequency of respiratory infections since using the SoClean 2 Device. After she started to use her SoClean 2 Device, Plaintiff Smith began experiencing eye irritation, respiratory tract irrigation, headaches, shortness of breath, and increasing frequency and/or severity of respiratory infections. Plaintiff Smith has suffered anguish and concern since it has been revealed that these products emit dangerous ozone.

7. Prior to purchasing charcoal filters for her SoClean device, Plaintiff Smith saw Defendant's claims that the filters converted activated oxygen to regular oxygen before release,

and she relied on these representations in purchasing the filters. During that time, based on Defendant's omissions and the false and misleading claims, warranties, representations, advertisements, and other marketing, Plaintiff Smith was unaware that these products have no measurable effect on ozone accumulation, and would not have purchased the filter or paid as much for it if that information was fully disclosed. Plaintiff Smith was injured by paying for a filter that has no or very little value—or whose value was at least less than what she paid—based on its ineffectiveness.

8. Defendant SoClean, Inc., is a Delaware corporation with its principal place of business at 12 Vose Farm Road, Peterborough, New Hampshire 03458.

JURISDICTION & VENUE

9. Subject Matter Jurisdiction. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d), because (1) the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are members of the Class who are diverse from Defendant, and (4) there are more than 100 class members.

10. Personal Jurisdiction. The Court has personal jurisdiction over SoClean because SoClean regularly conducts business in North Carolina and because SoClean has falsely advertised the product to consumers who reside in North Carolina. SoClean has also sold its products in the State of North Carolina. In addition, SoClean committed tortious acts in North Carolina, and Plaintiff's claims arise out of such acts, and/or because SoClean has otherwise made or established contacts in North Carolina sufficient to permit the exercise of personal jurisdiction.

11. Venue. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(d) and (c) and 18 U.S.C. § 1965, because SoClean is subject to personal jurisdiction in this judicial district and because a substantial part of the events giving rise to the claims in this action occurred

in this judicial district. Specifically, SoClean has run television, online, radio, and print advertising campaigns to promote its products, which reach the millions of consumers who reside in the United States, including in the Western District of North Carolina.

FACTUAL ALLEGATIONS

12. SoClean manufactures and sells medical devices that clean continuous positive airway pressure (“CPAP”) machines. Plaintiff Smith is the owner of a SoClean 2 CPAP cleaning device and used that device on a regular basis up until approximately one year ago.

I. Continuous Positive Airway Pressure Therapy

13. Continuous Positive Airway Pressure (“CPAP”) therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual’s throat to help individuals breathe.

14. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual’s sleep cycle. These interruptions, called “apneas,” are caused when the soft tissue in an individual’s airway collapses. The airway collapse prevents oxygen from reaching the individual’s lungs which can cause a buildup of carbon dioxide. If the individual’s brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual’s airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person’s lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person’s airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

II. Bi-Level Positive Airway Pressure Therapy

15. Bi-Level Positive Airway Pressure (“BiPAP”) therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or face mask device to maintain air pressure in an individual’s airway. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels – inspiratory and expiratory – of pressurized air into a person’s airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as the person inhales, and another level (the expiratory level) as a person exhales.

III. The Market for CPAP Sanitizing Devices

16. The SoClean devices are compatible with many brands of CPAP and BiPAP machines.

17. An estimated 8 million people in the United States use a CPAP machine.

18. CPAP machines are most commonly prescribed for sleep apnea, a potentially serious disorder in which an individual’s breathing repeatedly stops and starts while sleeping. The most common form of sleep apnea is caused by airway obstruction.

19. CPAP machines are also used to treat diseases such as pulmonary fibrosis and Chronic Obstructive Pulmonary Disease (“COPD”), an umbrella term used to describe progressive lung diseases characterized by increasing breathlessness.

20. While sleeping, a CPAP user wears a face mask, which is attached by a hose to a machine that pressurizes air.

21. Room air is drawn into the CPAP machine through an air intake and, once inside, the machine pressurizes the air. *See Ex. A (Airflow Diagrams), Figure 1.*

22. The pressurized air is then pumped from the CPAP's air outtake, through a hose, and into the facemask, delivering just enough air pressure to keep the user's upper airway passages open while sleeping. *See Ex. A (Airflow diagrams), Figure 1.*

23. Some CPAP machines also include a heated humidifier that is either fully integrated into the machine or easily attached. Use of the humidifier is optional; generally, it can either be turned off or detached.

24. CPAP users must regularly sanitize or disinfect their CPAP equipment.

25. The SoClean devices use ozone gas in an attempt to clean CPAP equipment.

26. The SoClean 2 and the SoClean 2 Go work similarly, but the SoClean 2 Go is a smaller, more portable version. *Compare Ex. B (SoClean 2 Photos), with Ex. C (SoClean 2 Go Photos).*

27. The SoClean devices are Class 1 medical devices subject to the Medical Device Amendments to the Food, Drug and Cosmetic Act ("FDCA") and the implementing regulations promulgated by the Food and Drug Administration ("FDA").

28. As Class I medical devices, the SoClean devices are not subject to premarket review by the FDA.

IV. FDA Regulation of Ozone

29. All medical devices must comply with the FDA's Maximum Acceptable level of Ozone Rule, 21 C.F.R. § 801.415 (2019).

30. The FDA's Maximum Acceptable Level of Ozone requirements took effect in 1974. *See* FDA Final Rulemaking: Ozone Generators and Other Devices Generating Ozone, 39 Fed. Reg. 13773-74 (Apr. 17, 1974).

31. The FDA has determined that “[o]zone is a toxic gas.” 21 C.F.R. § 801.415(a).

32. The FDA initially regulated ozone in medical devices because “[i]n order for it to be effective as a germicide, ozone must be present in a concentration far greater than that which can be safely tolerated by man and animals.” FDA Notice of Proposed Rulemaking, 37 Fed. Reg. 12644 (June 27, 1972); *accord* 21 C.F.R. § 801.415(a) (same).

33. The FDA found that “in tests conducted to study the bactericidal properties of ozone, test animals have died before the bacteria were completely destroyed.” FDA Notice of Proposed Rulemaking, 37 Fed. Reg. 12644 (June 27, 1972).

34. The FDA has determined that ozone exposure causes “undesirable physiological effects on the central nervous system, heart, and vision” and “the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema.” 21 C.F.R. § 801.415(b).

35. FDA regulations make it illegal for a medical device to “generate [] ozone at a level in excess of .05 part per million by volume of air circulating through the device....” 21 C.F.R. § 801.415(c)(1).

36. FDA regulations make it illegal for a medical device to “cause [] an accumulation of ozone in excess of .05 part per million by volume of air ... in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices.” 21 C.F.R. § 801.415(c)(1).

37. FDA regulations make it illegal for a medical device to “generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm.” 21 C.F.R. § 801.415 (c)(2).

38. FDA regulations make it illegal for a medical device “[t]o generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed .05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of .05 part per million.” 21 C.F.R. § 801.415(c)(3).

V. Ozone Gas

39. Ozone (O₃) is an unstable blue gas with a pungent characteristic odor.

40. Ozone gas forms when oxygen molecules (O₂) interact with electricity and recombine with oxygen atoms (O) to form ozone (O₃).¹

41. Because ozone is an unstable gas, over time it gradually breaks down by recombining with other molecules to re-form oxygen (O₂).

42. In still air at room temperature, studies show it can take up to twenty-five hours for ozone levels to reduce by half,² and ozone continues to break down at this rate until it dissipates.

¹ Oxygen atoms (the “O” on the periodic table of elements) and oxygen molecules (the O₂ that we breathe are both commonly called oxygen.

² J.D. McClurkin & D.E. Maier, “Half-Life time of Ozone as a Function of Air Conditions and Movement,” Presentation at the 10th Int’l Working Conf. on Stored Product Protection (2010), <http://works.bepress.com/dirk-maier/44/> (finding that ozone’s half-life varies based on atmospheric conditions with a maximum half-life of 1,524 minutes (25 hours) in dry still cool air) (last visited June 1, 2022).

43. When ozone encounters organic material, its third oxygen atom can detach from the ozone molecule and re-attach to molecules of the other substance, thereby altering the chemical composition of the other substance.

44. This reaction, called oxidation, can kill bacteria, viruses, and odors.

45. In sufficiently large quantities, ozone is also toxic to human beings.

46. In smaller quantities, breathing ozone for even a short time can cause adverse health consequence in human beings.

47. Ozone inhalation predominantly affects the respiratory system, and can cause irritation, pulmonary edema, and reduced lung function.

48. Breathing ozone can cause coughing and shortness of breath.

49. Breathing ozone can compromise the body's ability to fight respiratory infections.

50. Breathing ozone can worsen asthma symptoms.

51. Breathing ozone can worsen symptoms in people with heart disease.

52. Ozone can react with other chemicals in the air to produce additional chemicals and fine particles that can also be irritating to the eyes, nose, throat, and lungs.

VI. SoClean's CPAP Sanitizing Process

53. The SoClean devices sanitize CPAP machines by generating ozone and circulating it throughout the user's CPAP equipment.

54. The SoClean devices work on a variety of different CPAP models and can be used on CPAPs with or without humidifiers.

55. Each SoClean device features an ozone generator, a black hose with a connector, and a chamber. *See* Ex. B (SoClean 2 Photos), Figure 1; Ex. C (SoClean 2 Go Photos), Figures 1-2.

56. The SoClean 2 has a hard-plastic box as the chamber. *See* Ex. B (SoClean 2 Photos), Figures 1-2.

57. Inside the SoClean 2's chamber, there is a spot for a filter cartridge. *See* Ex. B (Photos of SoClean 2 Device), Figure 1.

58. The SoClean 2 Go uses a cloth bag with a draw string as the chamber. *See* Ex. C (SoClean 2 Go Photos), Figures 1,4.

59. On the SoClean 2 Go's cloth chamber, there is an outside pocket for a filter cartridge. *See* Ex. C (Photos of SoClean 2 Go Device), Figure 4.

60. The approximately 3.5" long and 1" square filter cartridges consist of a plastic shell filled with granulated charcoal.

61. SoClean makes and markets replacement filter cartridges to SoClean owners and represents that the filter must be replaced every six months for the life of the machine.

62. To set up a SoClean device initially, a user connects the black hose to his CPAP tank's air output opening, where the face-mask hose also attaches. *See* Ex. B (SoClean 2 Photos), Figure 3; *See* Ex. C (SoClean 2 Go Photos), Figure 2.

63. Connecting the black hose sometimes requires an adapter specific to the user's CPAP model.

64. Once connected, the black hose remains attached to the user's CPAP even while the SoClean device is not in use.

65. SoClean recommends that its customers run at least one cleaning cycle every day.

66. During a cleaning cycle, the SoClean device actively generates ozone for approximately 7 to 14 minutes.

67. To run a cleaning cycle, the user places his face mask into the SoClean device's chamber and closes the lid or draw string. *See* Ex. B (SoClean 2 Photos), Figure 2; Ex. C (SoClean 2 Go Photos), Figure 1.

68. The user can then manually initiate a cleaning cycle by pressing a button or series of buttons.

69. Alternatively, the SoClean 2 automatically runs a cleaning cycle every day when its digital clock reads 10:00 AM.

70. When a cleaning cycle starts, the SoClean device begins generating a large quantity of ozone gas that travels through the black hose into the CPAP's tank.

71. From the CPAP's tank, some of the ozone travels to the face mask and accumulates inside the SoClean device's chamber.

72. By design, this process inundates the CPAP mask, hose, and tank with ozone, killing bacteria, viruses, and odors found within.

73. During a cleaning cycle, the SoClean 2 consistently generates 30 ppm of ozone by volume of air circulating through the device. *See* Ex. D (SoClean 2 Lab Reports) at 1.

74. Within a SoClean device's chamber, 140 ppm of ozone accumulates during a cleaning cycle.

75. During and after a cleaning cycle, ozone escapes a SoClean device in two ways.

76. First, ozone is pumped into the user's CPAP machine and because CPAP machines are not airtight, that ozone vents into the user's bedroom.

77. This occurs because a CPAP machine has an open-air path between its air intake (where room air enters the machine to be pressurized) and its air outlet (where the face mask and the SoClean device connect to the machine). *See* Ex. A (Airflow Diagrams), Figure 1.

78. Accordingly, ozone that enters the CPAP's air outlet (where the SoClean and face mask attach) can freely escape through the CPAP's air-intake opening. *See* Ex. A (Airflow Diagrams), Figure 2.

79. Leaks can also “occur at tubing connections, filters or through fabric containers used to house CPAP accessories.”³

80. Anyone in proximity to the device can then inhale the escaped ozone.

81. As the FDA has warned, when ozone escapes, “ozone gas in the nearby space may temporarily rise to unsafe levels, especially if the space is not well ventilated.”⁴

82. SoClean users generally keep their SoClean devices attached to their CPAP machines in the bedroom on a bedside table, as consistently depicted by SoClean in marketing materials. *See, e.g.*, Ex. F (SoClean Marketing Materials), Figures 1-2.

83. When a SoClean 2 is run for 12 minutes, 28 ppm of ozone escapes the device and accumulates in a 50-liter Teflon chamber – with or without a filter cartridge installed. *See*, Ex. D (SoClean 2 Lab Reports) at 2-3.

84. This is 560 times the FDA's limit on ozone generation and accumulation by medical devices. *See* 21 C.F.R. § 801.415(c)(1).

85. When a SoClean 2 Go is run for 10 minutes, 5.6 ppm of ozone escapes the device and accumulates in a 27-liter glass chamber – with or without a filter cartridge installed. *See* Ex. E (SoClean 2 Go Lab Report).

³ *See* “Potential Risks Associated With The Use of Ozone and Ultraviolet (UV) Light Products for Cleaning CPAP Machines and Accessories: FDA Safety Communication,” [hereinafter Potential Risks], <https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and> (last visited June 1, 2022).

⁴ *Id.*

86. This is 112 times the FDA's limit on ozone generation and accumulation by medical devices. *See* 21 C.F.R. § 801.415 (c)(1).

87. Second, ozone remains in the CPAP mask, hose, and tank after a cleaning cycle.

88. During normal CPAP use, the user inhales this leftover ozone through the face mask as air from the CPAP machine flows into the mask.

89. SoClean does not advise users of the risk posed by remaining ozone.

90. Buried in the user guides, SoClean advises users to leave the mask in the SoClean device for two hours "to achieve maximum sanitizing," SoClean 2 Go User Guide at 12, or so that "all disinfecting is complete," SoClean 2 User guide at 16.

91. The SoClean 2 Go User Guide never warns that the two-hour post-cycle waiting period is intended to avoid exposure to unsafe levels of toxic gas. The SoClean 2 User Guide, in an unrelated FAQ on page 18, states: "The activated oxygen disinfects your equipment and naturally breaks down to regular oxygen within two hours." However, the SoClean 2 User Guide never links the waiting period is intended or required to allow toxic gas to dissipate.

92. But the ozone within the CPAP mask, hose, and tank does not breakdown within two hours.

93. During testing, ozone levels remain at 3 ppm two hours after a SoClean's cleaning cycle was complete. *See* Ex. D (SoClean 2 Lab Reports) at 4.

94. When using their CPAP after a cleaning cycle, users often complain of a strong odor.

95. The odor is attributable to ozone gas that remains in the CPAP mask, hose, and tank.

96. The FDA's Maude database, where consumers can report adverse experiences with medical devices, contains thousands of reports about SoClean, attributing adverse effects to unwitting ozone exposure. These reports include the following consumer complaints:

- a. "I purchased a soclean c-pap-cleaner. I followed all of the directions i.e., prepped the unit, hoses etc. I then cleaned the cpap machine using soclean at the recommended settings. That evening i slept with the cleaned machine. The smell of ozone was strong. The mfr calls ozone activated oxygen. After about 6 hours, i experienced a severe asthma attack which i have never had before. Treatment with rescue inhaler, steroids, bronchodilators. I have cough predominant asthma. The coughing was so severe that i injured my back."⁵
- b. "Purchased a soclean 2 cpap sanitizer from apria direct health care. Upon using machine, a strong odor was noted on mask, but was told this was normal and that it was like the ocean smell. After the first week i began having trouble with my breathing. It continued to get worse. Started breathing treatments and prednisone did not help. I then found out that they used ozone to sanitize the cpap machine. Checked the (b)(6) clinic web site only to find ozone is an irritant and can cause asthma attacks. Called apira direct and they told me to return the machine. They do not advise you of this danger. I ended up in an urgent care center today for the asthma attack."⁶
- c. "After approximately 3 months of using soclean 2 cpap cleaner i noticed i was getting sick, started having chest pains for short periods of time each day and felt tired all the time. After research of the product, found it uses ozone to disinfect and found i had most of the symptoms of excess ozone in my system. After 3 days of not using it i am feeling much better with no instances of chest pain and my cold is going away along with my lungs clearing up. I will be seeing my doctor in 2 weeks to be referred to a cardiologist for assessment."⁷

⁵ MAUDE Adverse Event Report: *Inceptus SoClean 2*, FDA (Sept. 10, 2016), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=5969746&pc=LRJ (last visited June 3, 2022).

⁶ MAUDE Adverse Event Report: *SoClean2 CPAP Sanitizer*, FDA (Mar. 12, 2018), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7472673&pc=LRJ (last visited June 1, 2022).

⁷ MAUDE Adverse Event Report: *SoClean Inc. SoClean Disinfectant, Medical Devices*, FDA (Mar. 12, 2018),

- d. “I used the soclean cpap cleaning machine, after i purchased it for (b)(6). It used ozone to cleanse cpap machine. There was ozone residue left in my cpap after using the soclean, and that ozone residue burned my sinuses and lungs. This product is hazardous to people's respiratory systems and it causes pain. It caused me severe pain. This product is unregulated and it should be regulated. I went to the doctor and was told to discontinue use of the soclean machine.”⁸
- e. “I purchased a soclean2 pap disinfecting device on (b)(6) 2018, from (b)(6) center in (b)(6), to clean my cpap unit. Since using the product from that time, i have noticed my sense of taste and smell have diminished dramatically as well as a very dry and an unusual taste in my mouth. Everything i eat tastes bland. Can you tell me if this product has side effects that are causing me these issues? i have not changed anything else in my diet. Including no new medications. Is there residue left from the cleaning that are irritating my mucous membranes? i have appointments to see a pulmonary and nose/throat specialist as well as my dentist to rule out any other medical issues. As i mentioned before, there have been no changes to my diet or lifestyle and current blood tests show no issues.”⁹
- f. “Since using soclean to disinfect my cpap i suffer difficulty and pain breathing. My lungs hurt. Shortly after waking in the morning i have nausea. Fda safety report id # (b)(4).”¹⁰

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7352173&pc=LRJ (last visited June 1, 2022).

⁸ *MAUDE Adverse Event Report: SoClean Inc. SoClean CPAP Cleaning Machine Disinfectant, Medical Devices*, FDA (May 1, 2017),

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=7805317&pc=LRJ (last visited June 1, 2022).

⁹ *MAUDE Adverse Event Report: SoClean, Inc SoClean2 CPAP Sanitizing Machine Disinfectant Medical Devices*, FDA (Feb. 20, 2019),

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8377760&pc=LRJ (last visited June 1, 2022).

¹⁰ *MAUDE Adverse Event Report: SoClean, Inc. SoClean2 Disinfectant, Medical Devices*, FDA (Apr. 1, 2021),

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12075158&pc=LRJ (last visited June 1, 2022).

- g. “I have been using the soclean cpap sanitizer for a little over 7 months and have been getting headaches and sinus issues lately. I thought it was related to spring allergies but after researching it seems that the ozone remaining in the sanitizing unit could be the culprit. Fda safety report id # (b)(4).”¹¹
- h. “Used a soclean 2 last night. It disinfected at 10:00am on (b)(6) 2021 and i went to bed at 10:00pm and when i put the mask on it had a strong odor. I put the mask on and eventually the smell went away. Used my cpap machine through the night. The next day, i was having trouble breathing and my lungs don't feel right. I used one time and my breathing is terrible. I am needing an inhaler. I am returning the product to apriadirect where i purchased it from. I called them and told them what happened and i need to return it. They just wanted to sell me a different machine. I will clean it myself going forward.”¹²
- i. “Used the soclean 2 cpap cleaning machine. The first night i immediately felt a headache (i suffer from migraine). The headache would last the majority of the next day and return each night. Night five, i had no headache when putting on my cpap mask which was taken right out of the soclean 2 machine (cleaned it 14 hours prior and let it sit in the closed machine to allow the ozone to dissipate) and immediately got a headache once i started breathing the air. Fda safety report id# (b)(4).”¹³

97. These experiences are representative of consumers’ experiences with ozone exposure through the SoClean devices.

¹¹ MAUDE Adverse Event Report: SoClean, Inc. SoClean CPAP Sanitizer Disinfectant, Medical Devices, FDA (May 3, 2021), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11938365&pc=LRJ (last visited June 1, 2022).

¹² MAUDE Adverse Event Report: SoClean, Inc. SoClean 2 Disinfectant, Medical Devices, FDA (May 27, 2021), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11912835&pc=LRJ (last visited June 1, 2022).

¹³ MAUDE Adverse Event Report: SoClean, Inc. SoClean 2 Disinfectant, Medical Devices, FDA (June 6, 2021), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12008122&pc=LRJ (last visited June 1, 2022).

98. As the FDA has summarized, it “has received reports from patients experiencing cough, difficulty breathing, nasal irritation, headaches, asthma attacks and other breathing complaints when ozone gas-based products were used to clean, sanitize or disinfect CPAP devices and accessories.”¹⁴

99. Similar consumer complaints can be found across the internet.

VII. SoClean’s False and Misleading Misrepresentations, Concealment, Half-Truths, and Omissions

100. SoClean has made misrepresentations, concealed and omitted material information, and spun half-truths about the SoClean devices’ ozone output across many forums, which are not only false but dangerous for consumers.

A. SoClean’s Failure to Disclose Its Ozone Generation and Use of the Term “Activated Oxygen”

101. The SoClean devices’ packaging does not disclose that the SoClean devices generate ozone or the levels of ozone generated.

102. Marketing materials for the SoClean devices do not disclose that they generate ozone or the levels of ozone generated.

103. Instead, SoClean represents to consumers that it uses “activated oxygen” to sanitize CPAP machines.

104. These omissions and representations are false and misleading.

105. The SoClean devices use ozone to sanitize CPAP machines.

¹⁴ Potential Risks, *supra* note 3.

106. As the EPA explains: “Manufacturers[, like SoClean,] and vendors of ozone devices often use misleading terms to describe ozone,” similar to activated oxygen, that “suggest that ozone is a healthy kind of oxygen.”¹⁵

107. However, “[o]zone is a toxic gas with vastly different chemical and toxicological properties form oxygen.”¹⁶

108. SoClean has represented across many forums that the SoClean devices use “activated oxygen.” For example:

- a. The product packaging for the SoClean 2 never mentions ozone and the box states: “Activated Oxygen powers through your CPAP reservoir, hose, and mask.” *See* Ex. G (SoClean 2 Packaging), Figure 6.
- b. SoClean’s website homepage does not mention ozone but states: “SoClean’s activated oxygen cleaning completely sanitizes your CPAP mask, hose, and reservoir without any water or chemicals.”¹⁷
- c. Since at least 2015, SoClean has used a promotional brochure advertising the SoClean devices that does not mention ozone and states: “SoClean’s activated oxygen completely sanitizes your mask, hose, and reservoir without any water or chemicals.”

¹⁵ *Ozone Generators that are Sold as Air Cleaners*, EPA (Nov. 27, 2018), <https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners> (last visited June 1, 2022).

¹⁶ *Id.*

¹⁷ SOCLEAN, www.SoClean.com (last visited Apr. 10, 2019).

- d. SoClean’s Amazon Store page for the SoClean devices states: “The SoClean CPAP Cleaner and Sanitizer uses activated oxygen to eliminate any germs and bacteria that may be lingering in your CPAP equipment. SHOP NOW.”¹⁸
- e. The SoClean 2 Amazon product page maintained by the company fails to disclose that the SoClean 2 generates ozone and states: “The SoClean CPAP sanitizing machine uses safe, natural, activated oxygen to thoroughly sanitize and disinfect your entire CPAP system.”¹⁹
- f. Previously, on the SoClean Website, in answer to the frequently asked question (“FAQ”) “Why do I smell ozone in my mask at night when the unit ran in the morning?” SoClean falsely stated: “What you smell is not ozone; the equipment is being oxidized with activated oxygen, and that is what you smell – it is completely safe. Some suggestions to lessen the smell: 1) Make sure you use the neutralizing pre-wash. 2) Increase the cleaning time to 12 minutes for a few weeks, then decrease to 7 minutes. 3) Blow air from your CPAP through your mask for 5 minutes before using it. 4) Do not use fragrance wipes or any fragrance products to clean your CPAP equipment, as this will intensify the smell.”²⁰

¹⁸ *SoClean: SoClean Devices*, AMAZON, https://www.amazon.com/stores/page/AA9FC37A-8D02-46CA-937C-CB1DF57940B7?ingress=2&visitId=2a75c335-30b8-4b76-a046-481679118819&ref_=bl_dp_s_web_9315360011 (last visited Apr. 20, 2019).

¹⁹ *SoClean 2 + Respironics DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter)* by SoClean, AMAZON, https://www.amazon.com/dp/B00JWVV4VW/ref=cm_sw_r_sms_awdb_t1_6D0UCbTKP73ZT (last visited Apr. 20, 2019).

²⁰ *SoClean and Activated Oxygen FAQs*, SOCLEAN, <https://www.soclean.com/sleeptalk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

- g. The 2014 and 2017 online versions of the SoClean 2 User Guide never mentions ozone and state that SoClean disinfects with “activated oxygen.”²¹
- h. The online version of the SoClean 2 Go User Guide never mentions ozone and states: “The SoClean 2 Go users no fluids in its operation. It sanitizes with activated oxygen. No fluids or water are used in this process.”²²
109. Buried deep within SoClean’s website are a user-support FAQ page and a “white paper” that disclose that “activated oxygen” is, in actuality, ozone.
110. The Brochure states: “The SoClean uses ozone – also known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”
111. The FAQ titled “What is Activated Oxygen” states:

Activated oxygen also known as ozone, or O₃ is defined by Merriam-Webster dictionary as: 1. a form of oxygen that is found in a layer high in the earth’s atmosphere. 2. fresh healthy air especially near the sea. Activated oxygen is a three atom oxygen molecule.

This three atom molecule is a colorless gas with powerful oxidizing properties, formed from oxygen by electrical discharges or ultraviolet light. it differs from normal oxygen (O₂) but over time or with forced filtration, will break back down to normal oxygen (O₂) that we breathe.

Many become confused over the term ozone. There is good ozone and there is bad ozone. Most commonly used is bad ozone which is linked to high ozone alerts or smog alerts in certain areas of the world. This kind of ozone is mixed with toxic gases that can be breathed in. Good ozone is found in our upper atmosphere, or you may smell the essence of ozone after a thunderstorm. Activated oxygen (ozone) is known as

²¹ 2017 SoClean 2 User Guide, SOCLEAN,
https://www.soclean.com/wpcontent/uploads/2017/03/soclean2_manual_RevH.pdf.

²² SoClean 2 Go User Guide, SOCLEAN,
https://www.soclean.com/wpcontent/uploads/2014/10/soclean2Go_manual_revA.pdf.

one of the best and most effective means to natural disinfection. This process is commonly used in array of applications such as public water filtration, fruit and vegetable handling, hotel housekeeping, and hospital disinfection. Please see common FAQs to learn more about activated oxygen (ozone) or see activated oxygen in SoClean to learn how the SoClean safely disinfects your CPAP equipment.”²³

112. Not only are the foregoing disclosures obscure and difficult to locate, but they are themselves affirmatively false and misleading.

113. The disclosures do nothing to cure SoClean’s falsehoods, omissions, concealments, and half-truths.

B. Representations that the SoClean Devices use “No Chemicals” and/or “No Harsh Chemicals”

114. SoClean misleadingly represents that its devices use “no water or chemicals” or “no harsh chemicals” to clean CPAP machines.

115. These representations are false and misleading.

116. The SoClean devices use ozone gas to clean CPAP machines.

117. Ozone is a chemical.

118. Ozone is a harsh chemical.

119. So Clean has repeatedly represented that its devices use “[n]o water or chemicals” or “no harsh chemicals” to clean CPAP machines across many forums. For example:

- a. The box for the SoClean 2 states: “No water or chemicals.” Ex. G (SoClean 2 Packaging), Figure 3.
- b. Since at least March 28, 2016, SoClean’s website homepage has read: “SoClean kills 99.9% of CPAP germs and bacteria in your mask, hose and reservoir with no

²³ *What is activated oxygen?*, SOCLEAN, <https://www.soclean.com/sleep-talk/documentation/activatedoxygen/> (last visited Apr. 16, 2019).

disassembly, no water, and no chemicals in order to enhance your home CPAP experience.”²⁴

- c. SoClean has aired the television commercial “Getting Sick from a Dirty CPAP” at least 10,929 times nationwide since 2018, representing that the SoClean devices use “no harsh chemicals” to clean CPAP machines.
- d. SoClean has aired the television commercial “CPAP Cleaner and Sanitizer” at least 22,058 times nationwide since 2016, representing that the SoClean devices use “no chemicals” to clean CPAP machines.
- e. SoClean has aired the television commercial “Safely Sanitize and Disinfect” at least 6,325 times nationwide between 2017 and July 2018, representing that the SoClean devices use “no harsh chemicals” to clean CPAP machines.
- f. SoClean has aired the television commercial “Automated CPAP Sanitizer” at least 512 times nationwide in 2018, representing that the SoClean devices use “no harsh chemicals” to clean CPAP machines.

C. Representations that the SoClean Devices Are “Safe” and “Healthy” for Use

- 120. SoClean often markets its device as “safe” and “healthy.”
- 121. These representations are false and misleading.
- 122. A device that releases toxic gas into a user’s bedroom at levels exceeding federal regulations is not “safe” or “healthy.”
- 123. SoClean has repeatedly represented that its devices are safe and healthy across many forums. For example:

²⁴ SOCLEAN, www.SoClean.com (last visited Apr. 10, 2019).

- a. The packaging for the SoClean 2 states: “Breathe Healthy, Breathe SoClean.” *See* Ex. G (SoClean 2 Packaging), Figure 4.
- b. Since at least March 28, 2016, SoClean’s website homepage has represented that the SoClean devices offer “Safe, healthier CPAP cleaning.”²⁵
- c. A brochure advertising the SoClean and SoClean 2 Go used since at least 2015 reads: “The SoClean makes it easy for any CPAP user to safely and naturally clean and sanitize their equipment on a daily basis.”
- d. A brochure advertising the SoClean and SoClean 2 Go used since at least 2015 reads: “Featuring the same safe, effective sanitizing process as the SoClean, the SoClean 2 Go is the perfect travel companion for any CPAP user – so small it can fit easily anywhere.”
- e. SoClean has aired the television commercial “Getting Sick from a Dirty CPAP” at least 10,929 times nationwide since 2018, representing that the SoClean devices help users stay healthy.
- f. SoClean has aired the television commercial “CPAP Cleaner and Sanitizer” at least 22,058 times nationwide since 2016, representing that the SoClean devices improve users’ health.
- g. SoClean has aired the television commercial “Safely Sanitize and Disinfect” at least 6,325 times nationwide between 2017 and July 2018, representing that the SoClean devices safely sanitize CPAP masks and hoses.
- h. In a brochure that consumers can obtain from SoClean only if they provide a name and valid email address, SoClean states that: “The SoClean users ozone – also

²⁵ SOCLEAN, www.SoClean.com (last visited Apr. 17, 2019).

known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”

- i. An Amazon product page maintained by the company reads: “The SoClean CPAP sanitizing machine uses safe, natural, activated oxygen to thoroughly sanitize and disinfect your entire CPAP system.”²⁶
- j. A SoClean FAQ page represents that: “What is the concentration of ozone inside the SoClean CPAP cleaner and sanitizer? SoClean uses enough ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm.”²⁷
- k. SoClean’s representations, advertisements, and written materials have been false in the past and continue to be false and misleading to the present.

D. Representations that the SoClean Devices Use the Same Sanitizing Process Used in Hospitals

124. SoClean represents that its devices use the same sanitizing process found in hospital sanitizing.

²⁶ *SoClean 2 + Respiromics DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter)* by SoClean, AMAZON, https://www.amazon.com/dp/B00FKBU0X6/ref=sspa_dk_detail_1?psc=1&pd_rd_i=B00FKBU0X6&pd_rd_w=9S2ks&pf_rd_p=80559f3c-f83b-49c1-8a72-40f936e9df7a&pd_rd_wg=4ucG4&pf_rd_r=BAAXN03P5HSPQ64V7BWZ&pd_rd_r=238c6796-5fee-11e9-97cc-7fd3667cd97a&smid=AC3UW2IWHXI2H (last visited Apr. 15, 2019).

²⁷ *SoClean and Activated Oxygen FAQs*, SOCLEAN, <https://www.soclean.com/sleeptalk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

125. This representation is false, misleading, omits crucial information, and conceals the differences between these processes.

126. Hospital ozone decontamination systems can only be used in vacant, sealed rooms.

127. Hospitals cannot and do not use ozone sanitizers in spaces occupied by patients.

128. SoClean devices, however, are marketed for use in the home, specifically bedrooms, and marketing materials often depict the SoClean device on the user's nightstand.

129. SoClean has repeatedly represented that its devices are used in hospital sanitizing across many forums. For example:

- a. Since at least 2015, SoClean has used a promotional brochure advertising the SoClean devices that includes:

Did you know that SoClean uses the same sanitizing process found in:



- b. Since at least 2015, SoClean has used a “rack card” advertising the SoClean devices that includes:

SoClean uses the same sanitizing process found in:



Water
Purification



Produce
Handling



Hotel
Housekeeping



Hospital
Sanitizing

www.SoClean.com

- c. The box for the SoClean 2 features a similar image that states: “SoClean uses the same sanitizing process found in:” “water,” “produce,” “hotels,” and “hospitals.” See Ex. G (SoClean 2 Packaging), Figure 5.
- d. The SoClean 2 Amazon product page maintained by the company reads “Activated oxygen[.] SoClean uses the same safe and proven sanitizing and disinfecting process found in water purification, produce handling, hotel housekeeping and hospital sanitizing.”²⁸
- e. In a brochure that SoClean requires consumers to provide a name and valid email address to obtain, SoClean states that: “The SoClean uses ozone – also known as O₃ or activated oxygen – to sanitize CPAP equipment. Ozone is a 100% safe, naturally occurring gas that has been used to purify water since the 1800s. In today’s world, it’s a trusted sanitizing process used by hospitals, food handlers and the hotel industry.”

²⁸ SoClean 2 + Respiroics DreamStation and System One Adapter (SoClean 2 CPAP Cleaner and Sanitizer Bundle with Free Adapter) by SoClean, AMAZON, https://www.amazon.com/dp/B00FKBU0X6/ref=cm_sw_r_sms_c_api_i_PCIVCb62EDG8E (last visited Apr. 21, 2019).

E. The Charcoal Filter Cartridges

130. SoClean represents that the filter cartridges convert “activated oxygen” back into “normal oxygen.”

131. This representation is false, misleading, omits crucial information, and conceals that there is no meaningful impact from the filters.

132. The FDA has determined that there is no reliable way to guarantee the rapid breakdown of ozone to prevent its accumulation in enclosed spaces. *See* FDA Final Ozone Rulemaking, 39 Fed. Reg. 13773, ¶ 6 (Apr. 17, 1974).

133. The filter does not prevent the SoClean devices from emitting ozone into the environment.

134. The SoClean filter does not prevent ozone from escaping into the atmosphere.

135. The SoClean filter has no measurable effect on ozone accumulation.

136. SoClean has repeatedly represented across many forums that its filters convert “activated oxygen” into “regular oxygen.” For example:

- a. The SoClean webpage selling replacement filters states that “[t]he Cartridge Filter converts activated oxygen back to regular oxygen as it leaves the SoClean 2 chamber.”²⁹
- b. The 2017 online version of the SoClean 2 User Guide states: “Additionally, any excess activated oxygen passes through a filter which converts it back to regular oxygen before release.”³⁰

²⁹ Cartridge Filter Kit – SoClean 2, SOCLEAN, <https://www.soclean.com/product/cartridge-filter-kit-soclean-2/> (last visited Apr. 15, 2019).

³⁰ 2017 SoClean 2 User Guide, SOCLEAN, https://www.soclean.com/wpcontent/uploads/2017/03/soclean2_manual_RevH.pdf.

- c. The online version of the SoClean 2 Go User Guide states: “This filter converts activated oxygen back into normal oxygen. Replace every 6 months.”³¹

F. Representations that SoClean Is a Sealed or “Closed-Loop” System

137. SoClean represents that the SoClean is a “closed system” and that no “activated oxygen” escapes the device.

138. This representation is false, misleading, omits crucial information, and conceals what the company knew or should have known about how the system worked.

139. A closed-loop system is one in which ozone circulates within but does not leave the device.

140. The SoClean devices circulate ozone through the CPAP machine which is then released into the ambient air or breathed by the CPAP user.

141. SoClean has repeatedly represented across many forums that its devices are a “closed system” and/or that no “activated oxygen” escapes. For example:

- a. A “CPAP cleaning demo video” hosted on the SoClean homepage shows “activated oxygen” circulating through the CPAP machine and SoClean device, but no “activated oxygen” escaping the CPAP machine during the cleaning process.³² *See* Ex. F (Marketing Materials), Figure 3. Online, the video appears next to the “Buy Now” button.
- b. A SoClean FAQ webpage represents the following: “What is the concentration of ozone inside the SoClean CPAP cleaner and sanitizer? SoClean users enough

³¹ 2014 SoClean 2 User Guide, SOCLEAN, https://www.soclean.com/wpcontent/uploads/2014/04/soclean2_manual_RevE.pdf.

³² SOCLEAN, <https://www.soclean.com> (last visited Apr. 21, 2019).

ozone to thoroughly sanitize your CPAP equipment and by the time you open the chamber it will have decreased to 0 ppm.”³³

c. The 2017 online version of the SoClean 2 User Guide states: “The SoClean produces activated oxygen in a closed system.”³⁴

d. The 2014 online version of the SoClean 2 User Guide states: “Is the SoClean harmful to me or the environment? No. The activated oxygen generator is always kept at a safe level and never reaches the outside environment.”³⁵

142. SoClean has made additional false and misleading representations, omitted additional material information, concealed critical information the company knew or should have known, and engaged in half-truths about the SoClean devices similar to those alleged above.

143. Upon information and belief, SoClean pays or otherwise incentivizes individuals to create blog posts and online reviews repeating the falsehoods, material omissions, and half-truths.

144. Upon information and belief, SoClean perpetuates the falsehoods, material omissions, and half-truths alleged above by using search engine optimization services.

G. The Effect of SoClean’s Misrepresentations, Omissions, Concealment, and Half-Truths

³³ SoClean and Activated Oxygen FAQs, SOCLEAN, <https://www.soclean.com/sleeptalk/documentation/soclean-activated-oxygen-faqs/> (last visited Apr. 16, 2019).

³⁴ 2017 SoClean 2 User Guide, SOCLEAN, https://www.soclean.com/wpcontent/uploads/2017/03/soclean2_manual_RevH.pdf.

³⁵ 2014 SoClean 2 User Guide, SOCLEAN, https://www.soclean.com/wpcontent/uploads/2014/04/soclean2_manual_RevE.pdf.

145. SoClean's misrepresentations, omissions, concealment, and half-truths deceive consumers into believing that the SoClean devices do not generate ozone, do not release ozone into the atmosphere, and are safe, healthy, and suitable for use in consumer's bedrooms.

146. SoClean's misrepresentations, omissions, concealment, and half-truths have allowed it to command a ninety-percent share of the market for CPAP sanitizing/sterilization devices.

147. SoClean's misrepresentations, omissions, concealment, and half-truths lead consumers to purchase SoClean's products when they would not otherwise do so.

148. Due to the nature of SoClean's business, its customers all have breathing problems for which they are receiving medical treatment in the form of CPAP therapy making them ill or infirm. In fact, CPAP users are so concerned about their health that they experience the considerable inconvenience of using a CPAP machine and wearing a CPAP face mask to sleep every night.

149. CPAP users would find the risk posed by the SoClean devices generating unsafe levels of toxic gas, which is then pumped into their CPAP machines and their bedrooms, material to their purchasing decisions.

150. SoClean's misrepresentations, omissions, concealment, and half-truths pose a threat to individual and public health.

151. Ozone exposure at levels exceeding .05 ppm negatively affects respiratory health.

152. Epidemiologic studies suggest that those with existing breathing problems may experience adverse symptoms of ozone exposure at concentrations even lower than .05 ppm.

153. SoClean's misrepresentations, omissions, concealment, and half-truths have actually deceived and harmed consumers.

TOLLING AND ESTOPPEL

I. DISCOVERY RULE TOLLING

154. Plaintiff and the Class had no way of knowing about SoClean's conduct with respect to the health risks associated with the use of the SoClean's devices.

155. Neither Plaintiff nor any other members of the Class, through the exercise of reasonable care, could have discovered the conduct by SoClean alleged herein. Further, Plaintiff and members of the Class did not discover and did not know of facts that would have caused a reasonable person to suspect that SoClean was engaged in the conduct alleged herein.

156. For these reasons, all applicable statutes of limitations have been tolled by the discovery rule with respect to claims asserted by Plaintiff and the Class.

II. FRAUDULENT CONCEALMENT TOLLING

157. By failing to provide immediate notice of the adverse health effects associated with continued use of the SoClean devices, SoClean concealed its conduct and the existence of the claims asserted herein from Plaintiff and the members of the Class.

158. Upon information and belief, SoClean intended its acts to conceal the facts and claims from Plaintiff and members of the Class. Plaintiff and the members of the Class were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Defendant's conduct. For this reason, any statutes of limitations that otherwise may apply to the claims of the Plaintiff or members of the Class should be tolled.

CLASS ACTION ALLEGATIONS

159. Plaintiff seeks certification on behalf of a class defined as follows (the "Class"):

All persons who were or are citizens of the State of North Carolina who purchased or used a SoClean device to clean and sanitize their CPAP, BiPAP, or Mechanical Ventilation machine.

160. Plaintiff reserves the right to modify or refine the definitions of the Class based upon discovery of new information and in order to accommodate any of the Court's manageability concerns.

161. Excluded from the Class are: (a) any Judge or Magistrate Judge presiding over this action and members of their staff, as well as members of their families; (b) Defendant's and Defendant's predecessors, parents, successors, heirs, assigns, subsidiaries, and any entity in which Defendant or its parents have a controlling interest, as well as Defendant's current or former employees, agents, officers, and directors; (c) persons who properly execute and file a timely request for exclusion from the Class; (d) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (e) counsel for Plaintiff and Defendant; and (f) the legal representatives, successors, and assigns of any such excluded persons.

162. **Numerosity (Rule 23(a)(1)).** The Class is so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class, as herein identified and described, is not known, but upon information and belief, the Defendant sold its products to millions of individuals.

163. **Commonality (Rule 23 (a)(2)).** Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual Class members, including the following:

- whether Defendant owed a duty of care to Plaintiff and the Class;
- whether Defendant knew or should have known that its products posed health risks;
- whether Defendant wrongfully represented that its products were safe;
- whether Defendant wrongfully represented that its products were safe to use;

- whether Defendant wrongfully failed to disclose that ozone that was produced by, used in, and escaped from, its products posed health risks users;
- whether Defendant's representations, omissions, concealment, and half-truths in advertising, warranties, packaging, and/or labeling were false, deceptive, and/or misleading;
- whether those representations and omissions were likely to deceive a reasonable consumer;
- whether a reasonable consumer would consider the presence, or risk of, health risks as a material fact in purchasing one Defendant's products;
- whether Defendant had knowledge that those representations, omissions, concealment, and half-truths were false, deceptive, and misleading;
- whether Defendant breached its express warranties;
- whether Defendant breached its implied warranties;
- whether Defendant engaged in false advertising;
- whether Defendant's conduct was negligent per se;
- whether Defendant made negligent and/or fraudulent misrepresentations and/or omissions; and
- whether Plaintiff and the members of the Class are entitled to actual, statutory, and punitive damages.

164. **Typicality (Rule 23(a)(3)).** Plaintiff's claims are typical of the claims of the other members of the proposed Class. Plaintiff and members of the Class (as applicable) suffered injuries as a result of Defendant's wrongful conduct that is uniform across the Class.

165. **Adequacy (Rule 23(a)(4)).** Plaintiff's interests are aligned with the Class they seek to represent. Plaintiff has and will continue to fairly and adequately represent and protect the interest of the Class. Plaintiff has retained competent counsel highly experienced in complex litigation and class actions and the types of claims at issue in this litigation, with the necessary resources committed to protecting the interest of the Class. Plaintiff has no interest that is antagonistic to those of the Class, and Defendant has no defenses unique to Plaintiff. Plaintiff and their counsel are committed to vigorously prosecuting this action on behalf of the members of the Class. Neither Plaintiff nor Plaintiff's counsel have any interest adverse to those of the other members of the Class.

166. **Superiority.** This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy, and joinder of all members of the Class is impracticable. The prosecution of separate actions by individual members of the Class would impose heavy burdens upon the Courts and Defendant, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class, and would be dispositive of the interest of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. Class treatment will create economies of time, effort, and expense and promote uniform decision-making.

167. **Manageability.** This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

168. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual

members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

CLAIMS FOR RELIEF

COUNT I

**BREACH OF EXPRESS WARRANTY
(on behalf of the Class)**

169. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

170. SoClean marketed and sold its products into the stream of commerce with the intent that its products would be purchased by Plaintiff and the Class.

171. SoClean expressly warranted, advertised, and represented to Plaintiff and the Class that its products were safe and appropriate for human use.

172. SoClean made these express warranties regarding its products' quality and fitness for use in writing through its website, advertisements, and marketing materials, and on its products' packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff and the Class entered in to upon purchasing Defendant's products.

173. SoClean's advertisements, warranties, representations, and omissions regarding health risks associated with its products, were made in connection with the sale of its products to Plaintiff and the Class. Plaintiff and the Class relied on SoClean's advertisements, warranties, representations, and omissions regarding its products in deciding whether to purchase and use SoClean's products.

174. SoClean's products do not conform to SoClean's advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease.

175. SoClean therefore breached its express warranties by placing its products into the stream of commerce and selling them to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by SoClean. These associated health effects substantially impair the use, value, safety of the products, and render them worthless.

176. SoClean was aware, or should have been aware, of the toxic or dangerous health effects of the use of its products, but nowhere on the package labeling or package inserts or on SoClean's websites or other marketing materials did SoClean warn Plaintiff and members of the Class that they were at risk of developing adverse health effects as a result of the dangerous ozone generated by, and used in, SoClean's products.

177. Instead, SoClean concealed the dangerous health effects of the ozone generated by, and used in, SoClean's products and deceptively represented that these products were safe, healthy, and appropriate for use. SoClean thus utterly failed to ensure that the material representations they were making to consumers were true.

178. The adverse health effects associated with use of SoClean's products existed when they left SoClean's possession or control and were sold to Plaintiff and members of the Class. The dangers associated with use of SoClean's products were undiscoverable by Plaintiff and members of the Class at the time of purchase of SoClean's products.

179. As manufacturers, marketers, advertisers, distributors and sellers of the products used by the Plaintiff and members of the Class, SoClean had exclusive knowledge and notice of the fact that its products did not conform to the affirmations of fact and promises.

180. In addition, or in the alternative, to the formation of an express contract, SoClean made each of the above-described representations and omissions to induce Plaintiff and members of the Class to rely on such representations and omissions.

181. SoClean's affirmations of fact and promises and its omissions were material, and Plaintiff and members of the Class reasonably relied upon such representations and omissions in purchasing and using SoClean's products.

182. All conditions precedent to SoClean's liability for its breach of express warranty have been performed by Plaintiff or members of the Class.

183. Affording SoClean an opportunity to cure its breaches of written warranties would be unnecessary and futile here. SoClean, in addition to having actual knowledge based on reasonable notice from user reports and its lab testing that the use of the SoClean and SoClean 2 by its customers, in the manner set forth in SoClean's own printed materials, such as advertisements and instructions, presented an unsafe medical situation to SoClean customers. SoClean had ample opportunity to stop using the ozone method in cleaning its customers' CPAP machines.

184. As a direct and proximate result of SoClean's breaches of express warranty, Plaintiff and members of the Class have been damaged because they did not receive the products as specifically warranted by SoClean. Plaintiff and members of the Class did not receive the benefit of the bargain and suffered damages at the point of sale stemming from their overpayment for SoClean's products.

185. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for SoClean's failure to deliver goods conforming to their express warranties and resulting breach.

COUNT II

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (on behalf of the Class)

186. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

187. SoClean is a merchant engaging in the sale of goods to Plaintiff and the Class.

188. There was a sale of goods from SoClean to Plaintiff and the Class, either directly or indirectly, by and through the Plaintiff's or Class members' medical providers and/or medical suppliers.

189. Plaintiff and the Class were foreseeable users of the product.

190. At all times mentioned herein, SoClean manufactured or supplied its products, and prior to being purchased by Plaintiff and the Class, SoClean impliedly warranted to them that SoClean's products were of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and omissions made on SoClean's products' labels and packaging, including that SoClean's products were safe and appropriate for human use. Plaintiff and the Class relied on SoClean's promises and affirmations of fact and omissions when they purchased and used SoClean's products.

191. Contrary to these representations and warranties, SoClean's products at the time of sale were not fit for their ordinary use and did not conform to SoClean's affirmations of fact and promises and omissions because use of SoClean's products is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these products.

192. SoClean breached its implied warranties by selling its products that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each product was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

193. SoClean was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the devices through user reports submitted to SoClean and through lab testing.

194. Privity exists because SoClean directly provides a warranty to, or has direct contact with, a buyer who purchases from a third party.

195. As a direct and proximate result of SoClean's conduct, Plaintiff and the Class have suffered actual damages in that each product they purchased is worth less than the price they paid and which they would not have purchased at all had they known of the attendant health risks associated with the use of each of SoClean's products.

196. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for SoClean's failure to deliver goods conforming to their implied warranties and resulting breach.

COUNT III

FRAUDULENT MISREPRESENTATION (on behalf of the Class)

197. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

198. SoClean failed to advise Plaintiff and the Class that SoClean's products posed serious health risks to their users and SoClean falsely represented to Plaintiff and the Class that SoClean's products were safe for human use.

199. SoClean intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiff and the Class to purchase SoClean's products.

200. SoClean knew that its representations and omissions about its products were false in that its products generated and used ozone and thus were at risk of causing adverse health effects to users of its products, which does not conform to the products' labels, packaging, advertising,

and statements. SoClean knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiff and the Class.

201. Plaintiff and the Class did in fact rely on these omissions and misrepresentations and purchased and used SoClean's products to their detriment. Given the deceptive manner in which SoClean advertised, represented, and otherwise promoted its products, Plaintiff's and the Class members' reliance on SoClean's omissions and misrepresentations was justifiable.

202. As a direct and proximate result of SoClean's conduct, Plaintiff and the Class have suffered actual damages in that they purchased SoClean's products (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known of the health risks associated with the use of SoClean's products, and (c) which did not conform to the products' labels, packaging, advertising, and statements.

203. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

204. Further Plaintiff and the Class shall be entitled to an award of punitive damages because SoClean's conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and/or was in reckless disregard and complete indifference to the probable consequence of its actions. Because SoClean put its own pecuniary interest ahead of all else, it sacrificed the safety, health, and well-being of consumers and their families. SoClean also unfairly profited off unsuspecting purchasers who believed they were buying a natural, safe, closed cleaning system. The only way to prevent this type of egregious indifference again is to assess punitive damages against Defendants.

COUNT IV

FRAUD BY OMISSION (on behalf of the Class)

205. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

206. SoClean concealed from, and failed to disclose to, Plaintiff and the Class that use of SoClean's products is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

207. SoClean was under a duty to disclose to Plaintiff and the Class the true quality, characteristics, ingredients and suitability of SoClean's products because: (a) SoClean was in a superior position to know the true state of facts about its products; (b) SoClean was in a superior position to know the risks associated with the use of, characteristics of, and suitability of its products for use by individuals; and (c) SoClean knew that Plaintiff and the Class could not reasonably have been expected to learn or discover prior to purchasing SoClean's products that there were misrepresentations and omissions by SoClean in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

208. The facts concealed or not disclosed by SoClean to Plaintiff and the Class were material in that a reasonable consumer would have considered them important when deciding whether to purchase SoClean's products.

209. Plaintiff and the Class justifiably relied on SoClean's omissions to their detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of SoClean's products, which is inferior when compared to how SoClean's products are advertised and represented by SoClean.

210. As a direct and proximate result of SoClean's conduct, Plaintiff and the Class have suffered actual damages in that they purchased SoClean's products (a) that were worth less than

the price they paid, (b) which they would not have purchased at all had they known of the health risks associated with the use of SoClean's products, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

211. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

212. Further Plaintiff and the Class shall be entitled to an award of punitive damages because SoClean's conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and/or was in reckless disregard and complete indifference to the probable consequence of its actions. Because SoClean put its own pecuniary interest ahead of all else, it sacrificed the safety, health, and well-being of consumers and their families. SoClean also unfairly profited off unsuspecting purchasers who believed they were buying a natural, safe, closed cleaning system. The only way to prevent this type of egregious indifference again is to assess punitive damages against Defendants.

COUNT V

NEGLIGENT MISREPRESENTATION (on behalf of the Class)

213. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

214. SoClean had a duty to Plaintiff and the Class to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of SoClean's products.

215. SoClean breached its duty to Plaintiff and the Class by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff and the Class that did not have the qualities, characteristics, and suitability for use as advertised by SoClean and

by failing to promptly remove its products from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of its products.

216. SoClean knew or should have known that the qualities and characteristics of its products were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by SoClean. Specifically, SoClean knew or should have known that: (a) the use of its products was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) its products were adulterated, or at risk of being adulterated, by the ozone the products generated, and used; and (c) the products were otherwise not as warranted and represented by SoClean.

217. As a direct and proximate result of SoClean's conduct, Plaintiff and the Class have suffered actual damages in that they purchased SoClean's products (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known they generated, and used, ozone that could cause users of the products to suffer adverse health effects, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

218. Plaintiff and the Class seek actual damages, attorneys' fees, costs, and any other just and proper relief available.

COUNT VI

UNJUST ENRICHMENT (on behalf of the Class)

219. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

220. Plaintiff and the Class directly conferred a benefit on SoClean through their purchase of its products. SoClean voluntarily accepted and enjoyed these benefits.

221. SoClean either knew or should have known that the payments rendered by Plaintiff and the Class were given with the expectation that SoClean's products would have the qualities,

characteristics, and suitability for use represented and warranted by SoClean. As such, it would be inequitable for SoClean to retain the benefit of the payments under these circumstances.

222. SoClean's acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for SoClean to retain the benefits without payment of the value to Plaintiff and the Class.

223. Plaintiff and the Class are entitled to recover from SoClean all amounts wrongfully collected and improperly retained by Defendant, plus interest thereon.

224. Plaintiff and the Class seek restitution, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT VII
**VIOLATIONS OF NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE
PRACTICES ACT,
N.C. Gen. Stat. §§ 75-1.1, *et seq.*
(on behalf of the Class)**

225. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

226. Plaintiff and Class members are "persons" within the meaning of N.C. Gen. Stat. §75-16.

227. Defendant is a firm or corporation within the meaning of N.C. Gen. Stat. §75-16.

228. At all times relevant herein, Defendant was engaged in or affecting commerce in the State of North Carolina within the meaning of N.C. Gen. Stat. §75-1.1(b).

229. The North Carolina Unfair and Deceptive Trade Practices Act (UDTPA) broadly prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." N.C. Gen. Stat. §75-1.1(a).

230. Defendant's conduct as set forth herein is "unfair" and violates the UDTPA because it is unethical, oppressive, unscrupulous, and substantially injurious to the consumers of North

Carolina and has the capacity and tendency to deceive the average consumer acting reasonably under the circumstances.

231. Defendant repeatedly advertised on its website, advertisements, and marketing materials, and on its products' packaging and labels that its products were safe and fit for human use. In addition to these representations and half-truths, Defendant failed to disclose the material information—namely, the risk of exposure to unsafe levels of ozone and/or developing adverse health effects as a result of the dangerous ozone generated by, and used in, SoClean's products—and therefore Defendants' products were unsafe and unfit for human use.

232. Defendant's false, misleading, and deceptive statements and representations of fact were and are directed to consumers in North Carolina.

233. Plaintiff and the Class reasonably relied on Defendant's false, misleading and deceptive statements and representations of fact in deciding to purchase SoClean's products.

234. Defendant's deceptive acts and practices in the form of these misrepresentations, concealment, omissions, and half-truths about SoClean's products were material because they involved information that would be important to the average consumer in making relevant purchasing decisions.

235. By affirmatively representing that SoClean's products were safe and fit for human use, Defendant assumed a duty to speak truthfully as to the products' characteristics and attendant risks, which it materially failed to do by its omissions and half-truths. And by actively concealing that SoClean's products generated or used ozone, Defendant knowingly took affirmative steps to conceal material facts from consumers, including Plaintiff and the Class who were ignorant and unable to discover the truth through reasonable diligence.

236. Defendant's unfair or deceptive acts or practices in the form of its

misrepresentations, concealment, omissions, and half-truths have resulted in consumer injury, including to Plaintiff and the Class.

237. As a direct and proximate result of Defendant's unfair or deceptive acts or practices, Plaintiff and the Class have suffered losses in the form of monetary and non-monetary damages, including that they purchased SoClean's products (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known they generated, and used, ozone that could cause users of the products to suffer adverse health effects, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

238. On account of these injuries, Plaintiff and the Class are entitled to actual damages in an amount not less than the price of the SoClean device, and treble damages, in accordance with N.C. Gen. Stat. § 75-16. Further, because Defendant willfully engaged in these unfair or deceptive acts or practices, Plaintiff and the Class are entitled to reasonable attorneys' fees and costs, as provided by N.C. Gen. Stat. § 75-16.1.

239. Finally, Defendant put its own pecuniary interest ahead of all else, and in the process sacrificed the safety, health, and well-being of Plaintiff and Class members. The only way to prevent this egregious conduct from recurring is to assess punitive damages against Defendant.

240. Plaintiff and the Class therefore seek all monetary and non-monetary relief allowed by law, including actual damages, treble damages, restitution, injunctive relief, punitive damages, and reasonable attorneys' fees and costs.

a. _____

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

- A. An order certifying this action on all counts, and the Class requested herein as a Class Action, designating Plaintiff as the representative of the Class and appointing Plaintiff's counsel as Class counsel for the Class.
- B. An order declaring that SoClean's actions constitute:
 - i. A breach of express warranty;
 - ii. A breach of implied warrant of merchantability;
 - iii. Fraudulent misrepresentation;
 - iv. Fraud by omission;
 - v. Negligent misrepresentation;
 - vi. Unjust enrichment;
 - vii. A violation of the North Carolina Unfair and Deceptive Trade Practices Act.
- C. A judgment that SoClean is liable to Plaintiff and the Class as described herein for damages;
- D. A judgment awarding Plaintiff and members of the Class all compensatory and punitive damages as is appropriate to be determined at trial;
- E. A judgment awarding Plaintiff and the Class pre-judgment and post-judgment interest in an amount prescribed by law, as well as any statutory trebling or other damages;
- F. A judgment awarding Plaintiff and the Class costs and fees, including attorneys' fees, as prescribed by law; and
- G. Grant such other legal, equitable, or further relief as the Court may deem just and proper.
- H. Plaintiff requests a trial by jury for all issues so triable.

RESPECTFULLY SUBMITTED, on July 5, 2022.

By: /s/ Joel R. Rhine
Joel R. Rhine
NC State Bar # 16028
RHINE LAW FIRM, P.C.
1612 Military Cutoff Road
Suite 300
Wilmington, NC 28403
Telephone: (910) 772-9960
jrr@rhinelawfirm.com

SHARP LAW FIRM
Ruth Anne French-Hodson
Sarah T. Bradshaw
4820 W. 75th St.
Prairie Village, KS 66208
Telephone: (913) 901-0505
rafrenchhodson@midwest-law.com
sbradshaw@midwest-law.com

MASON LLP
Gary E. Mason
Danielle L. Perry
5101 Wisconsin Ave., Suite 305
Washington, DC 20016
Telephone: 202.429.2290
gmason@masonllp.com
dperry@masonllp.com

**DEAKLE-JOHNSON LAW
FIRM, PLLC**
Ronald Verdell Johnson, IV
Russell L. Johnson
P.O. Box 2072
Hattiesburg, MS 39403
Telephone: (601) 544-0631
rljohnson@djlawms.com
rvjohnson@djlawms.com

*Counsel for Plaintiff Marguerite
Smith*